Note: This document is provided as a guide to assist in collecting required information. Protocols must be submitted electronically using the associated Google form.

# Faulkner University: Research Protocol Review Form

Form for Research with Human Participants

* Required

1. **Email address** *

2. **Name of person completing this form** *

## INSTRUCTIONS

Complete each section of the form before submitting. If any section does not apply, enter "n/a" in the appropriate box.

## SECTION I: General Information

3. **Title of your project** *

4. **Date of submission (today's date)** *

*Example: December 15, 2012*

5. **List the primary researcher or faculty supervisor** *

6. *

*Mark only one oval.*

- ◯ Primary Investigator
- ◯ Faculty Supervisor (for student projects)

7. **List all other researchers, their titles, e-mails, and the role in the project (e.g. John Doe; Student; Student researcher; Mary Jane; Faculty; Co-Researcher)**

## Requested Approval Type

(Note: Final determination is the decision of the IRB)"Minimal Risk" is defined by the Revised Common Rule rule (45 C.F.R. § 46.102(j)) as: "Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests."

*Exempt reviews must still be submitted to the IRB for consideration and verification of status except those considered Excepted such as internal assessments or classroom projects that pose no reasonable concern for risk. Contact irb@faulkner.edu for questions regarding this category.

8. **Type of Review** *

*Mark only one oval.*

- ◯ Full Board (greater than minimal risk to humans or non-human animals, use of hazardous materials, any greater than minimal risk to society or the environment)
- ◯ Expedited Review (minimal or less than minimal risk to humans, non-human animals, and the environment)
- ◯ Exempt Review* (no risk to humans, non-human animals, society, or the environment, or as defined by the July 19, 2018 Revised Common Rule); *Note that all research conducted as an agent of Faulkner University should be submitted for review. Exempt applications are important for records of research conducted, and so the IRB can verify the review type.
- ◯ Request access to Faulkner students or employees (Other University approved IRB must be attached or submitted via irb@faulkner.edu)

9. **Explanation for justification of Expedited or Exempt Review (optional):**

# SECTION II: Project Summary

## Abstract/Summary

*Provide an abstract or project summary outlining the basic tenets of the research project (400 words or less). A proposal draft may be submitted as an appendix in lieu of this section. E-mail to irb@faulkner.edu referencing your project title in the e-mail.

10. **Abstract / Summary** *

## Project Purpose

Provide a summary of the purpose and details of the project. The summary should include rationale for the research, hypothesis, goals / objectives, and intended use of the study results (e.g. internal use, publication, conference, course requirement, etc.). This should be written in non-technical language understandable by a person unfamiliar with this area of research.

11. **Project Purpose** *

## Content Areas

List all applicable research content or discipline areas (e.g. biology, chemistry, psychology, education, history, journalism, etc).

12. **Content Areas** *

## SECTION III: Participants, Privacy, and Risks

13. **Describe the intended population and participant characteristics (provide sufficient details)** *

14. **Will Faulkner students or employees be recruited to participate?** *

*Mark only one oval.*

- ◯ Students
- ◯ Employees
- ◯ Both
- ◯ Neither

15. **How many participants will be sought for this project? (minimum to maximum)** *

_____

16. **Vulnerable Participants** *

Will the participants include any of the following vulnerable or at-risk population groups?
*Check all that apply.*

- ☐ NONE
- ☐ Children/minors
- ☐ Prisoners
- ☐ Institutionalized persons
- ☐ Students (as part of a course or degree requirement)
- ☐ Pregnant women
- ☐ Fetuses/Neonates
- ☐ Mentally challenged persons
- ☐ Non-English speaking persons (if known)
- ☐ Educationally or developmentally challenged persons
- ☐ Economically challenged persons
- ☐ Other: _____

17. **Participant Protections** *

Describe what protections will be in place, including those to avoid potential coercion or undue influence, informed consent (submit a copy of the consent form to be used), as well as any debriefing procedures or services. [Note: Vulnerable populations require additional protections be explained in this area related to the additional potential risk].

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18. **Describe all potential risks and benefits to participants and to society. The estimated degree of risk and potential may also be included. [Note: This question is a key component to the IRB decision making process!] Risks may include (but are not limited to) deception, coercion, breach of confidentiality, intrapersonal or psychological conflict, invasion of privacy, economic risks, revelation of illegal activity, risk of bodily harm, etc.** *

19. **List any compensation, inducements, or incentives offered. Provide justification for their inclusion, and assurance they will not be used as means of coercion. (Note: Monetary or like-kind inducements greater than what would be considered a "thank-you", or reimbursement of expenses are generally not approved).** *

*Skip to question 19.*

## Data and Procedures

20. **Describe what data will be collected, and the procedure used to collect it. Note if data to be collected is archived data, publicly available, or any other special characteristics.** *

21. **Describe the tests, measures, surveys, etc. to be used for data collection. [If items are published and publicly available, include references or website links. If items are unpublished or otherwise not publicly available, include copies as an attachment to this form).** *

22. **Describe the methods of analysis and measures (e.g. statistical procedures, qualitative/quantitative/mixed analysis methods, etc.)**

23. **List and describe all locations and organizations where data is to be collected, and how permission will be obtained (if applicable) to access participants. [Note: In most cases, permission is required to access any participant groups affiliated with any type of organization (institution, school, business, government entity, etc.). Some require IRB approval prior to gaining access to participants. Researchers are cautioned to verify requirements and obtain necessary organizational permissions prior to any attempts to recruit participants from other organizations. Access to participants affiliated with Faulkner may be granted by the IRB. However, additional administrative approval may be required in some cases.]** *

24. **Will data be collected as prospective (e.g. surveys to be completed, samples to be collected, interviews to be conducted) or retrospective (e.g. existing data, archival data, historical records), or both. [For example: A researcher may collect data on people who lived in an area exposed to radiation during the last 10 years (retrospective), recruit a selective sample of those people to collect blood samples and a health assessment (prospective) in the same project.]** *

*Mark only one oval.*

- ◯ Prospective
- ◯ Retrospective
- ◯ Both

25. **What is the latest date the data collection may take place? Approval period will be based on this date, so choose the latest date data collection is likely to span. [Note: Longitudinal studies may require continuing approval or periodic reporting and assurance.]** *

*Example: December 15, 2012*

26. **Will the data be collected as anonymous (no means of identifying participants), confidential (only researchers can match participants to data), identifiable (the public will or could know who participated in the study and match data collected to individuals), or other? Describe any coding used to identify and/or protect participants and data.** *

*Mark only one oval.*

- ◯ Anonymous
- ◯ Confidential
- ◯ Identifiable
- ◯ Other: _____

27. **Where and how will data be stored?** *

_____

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28. **How long will data be retained? (Note: Many discipline standards and publications require retention of anonymous data indefinitely, or confidential data for 7-10 years after completion of project or publication to be made available for other researchers and verification purposes).** *

_____

29. **When and how will data be destroyed if applicable?** *

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30. **Who will have access to the data until destroyed? How will it be made available for inspection by other researchers or for verification purposes?** *

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31. **How will the results of the research be used and disseminated (e.g. publication, conference presentation, educational dissemination)? ***

## Assurances

32. **Financial and Conflicts of Interest: List any and all sources of funding for the project, any forms of remuneration to researchers, assistants, or others involved in the research, and any potential financial or other possible conflicts of interests whether financial, personal, or otherwise. Copies of grant approvals or other relevant documentation may be indicated here and included as an appendix. ***

33. **Qualifications and Training of Researchers: Please list applicable human subjects ethics course completion and dates completed by each individual involved in the project involving human subjects research. Ethical and federal guidelines require researchers to be competent in the principles of the research they conduct or oversee. Researchers (generally including students, assistants, and others involved in the project) are required to have completed an approved human subjects ethics course or refresher course within the last 5 years (3 years recommended if applicants have not been regularly engaged in human subjects research or ethics training). Unless specifically exempt, researchers engaged with research with human subjects must have completed an approved human subjects ethics training course such as the CITI training course, or the now defunct NIH-PHRP course. Faulkner University maintains an institutional license for several CITI training courses which allows members affiliated with the University to take this course without charge to them or their department. Contact the CAREE office or e-mail irb@faulkner.edu for more information. Researchers must submit a copy of the certificate or transcript to the IRB as an appendix to this form as verification of competency in conducting research with human participants. Researchers conducting specialized research areas may also be required to verify competency in the specialized area, some of which may also be available through the University institutional license at no charge to the researcher.**

## File Upload

34. **Upload all files here. Typical files include full proposals, abstracts, sample consent forms, institution access approval letters, ethics training certificates, or other supplemental information.**
    Files submitted:

## Signature/Approval

By signing [including electronically below] this application, I/we agree that all information contained herein is true and correct to the best of my/our knowledge. All applicable information has been disclosed. Further, assurance is given that research will conducted only within the approval guidelines and parameters, and that all ethical, moral, legal, and discipline specific expectations of conduct will be followed. Should any relevant portion of the research approval need to be changed, a revised approval will be sought before conducting or continuing research.
Further, it is acknowledged that IRB approval does in no way release the researchers from guilt, liability, or culpability in legally and ethically conducting research and protection of participants. Competency of all individuals involved has been verified and assured. All data analysis and reporting will be conducted with complete and total transparency and accuracy.

Note: The IRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements, legal or ethical guidelines, or that has been associated with unexpected serious harm to humans, animals, or society.

Additional signatures via hard copy or e-mail verification may be required if/as applicable.

Completing the section below constitutes an electronic and binding signature. A person completing this form on behalf of the primary investigator must do so with consent of the P.I. Students completing this form for a student project must do so with consent of their faculty supervisor.

35. **Name and title** *

36. **E-mail** *

37. **Today's date** *

*Example: December 15, 2012*

A copy of your responses will be emailed to the address you provided